UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

7/1/2019

SUBJECT: Acute Toxicity Review for *Tail*,
EPA Reg. No.: 5813-REG

FROM: Ian Blackwell, M.S., Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Lindsay O'Dell, Acting Team Leader
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TO: Eric Miederhoff, PM Team 31 / Emilia Oiguenblik
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: The Clorox Company		
Decision No.: 548501	Submission No.: 1030824	E-Sub No.: 36085
DP No.: 451331	Action Code: A540	
MRID No(s).: 50749703, 50749704		

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
169101	68989-02-6	Alkyl dimethyl benzyl ammonium chloride	1.480
069149	7173-51-5	Didecyl dimethyl ammonium chloride	0.555
069165	32426-11-2	Octyl decyl dimethyl ammonium chloride	1.110
069166	5538-94-3	Dioctyl dimethyl ammonium chloride	0.555
		Other Ingredients	96.300
		Total	100.00

I) **BACKGROUND**:

The registrant, The Clorox Company, has submitted an application for pesticide registration for their product: *Tail,* EPA File Symbol 5813-REG. *Tail* is intended to be a laundry sanitizer for use in the final rinse cycle of the washing machine.

In support of the acute toxicity data requirements of the subject product, the registrant seeks to do the following:

1) The Clorox Company plans to use an acute oral toxicity conducted using this formulation; it was assigned MRID Number 5049703.
2) They ask to cite the toxicity category from the acute above oral toxicity category to support the **acute dermal toxicity** data requirement. This citation is in accordance with the Agency document, Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations & Supporting Retrospective Analysis, November 9, 2016.
3) For the acute inhalation toxicity requirement, the registrant asks for a waiver based upon the inability to inhale a toxic concentration, low volatility, and the lack of aerosols being formed.
4) The registrant seeks to waive the primary eye and skin irritation studies based upon the total percentage of quaternary ammonium compounds in this product and receive toxicity category I for both data requirements. This waiver guidance is found in the Agency document, Product Reregistration Batching Guidance for Quaternary Ammonium Compounds (Cases 0350 and 3003) – Acute Mammalian Toxicity Data Requirements, 2/9/2015.
5) The registrant requests a waiver of the dermal sensitization study based upon the product being classified toxicity category I for primary skin irritation. This particular waiver guidance is found in the 40 CFR §158.500.

II) **FINDINGS/RECOMMENDATIONS**:

1) **Acute Oral Toxicity**: The acute oral toxicity study is acceptable.

2) **Acute Dermal Toxicity**: The Agency allows the registrant to cite the acute oral toxicity study to determine the acute dermal toxicity category of this product.

3) **Acute Inhalation Toxicity**: The Agency waives the acute inhalation toxicity study due to the reported viscosity of the registration product, 50 cps. This viscosity is similar to that of corn oil or SAE 10 motor oil. It is not expected to be aerosolizable nor respirable. The lab did not provide enough information to assess the volatility of the overall formulation, nor, a particle-size determination to measure the inhalability of the product.

4) **Primary Eye and Skin Irritation**: The Agency waives the requirement for these two studies and assigns each toxicity category I based upon the Product Reregistration Batching Guidance for Quaternary Ammonium Compounds (Cases 0350 and 3003) – Acute Mammalian Toxicity Data Requirements. In that document, File Symbol 5813-REG would be classified as a product with "greater than 0.50% total quat", that may accept a toxicity category I for primary eye and/or skin irritation.

5) **Dermal Sensitization**: The Agency waives the requirement for the dermal sensitization study for EPA File Symbol 5813-REG.

III) The acute toxicity profile of Tail, EPA Reg. No. 5813-REG is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	50749703	IV	Acceptable
Acute Dermal Toxicity	50749703	IV	Cited
Acute Inhalation Toxicity	50749704	IV	Waived
Primary Eye Irritation	50749704	I	Waived
Primary Skin Irritation	50749704	I	Waived
Dermal Sensitization	None	Nonsensitizer	Waived

IV) PRODUCT LABELING

1) **Signal Word:** DANGER

2) The statement, "Keep Out of Reach of Children (KOROC)", is required. It should appear immediately above the front-panel signal word "DANGER".

3) The Agency's Label Review Manual

(https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf) indicates the following human-hazard precautionary statements:
PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
"Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear safety glasses, goggles or face shield. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse."

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

4) This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye and skin irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.

5) Based upon data placing it in toxicity category I for primary eye and skin irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP in addition to Restricted-Use Classification. CRP requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (870.1100)

Product Manager:	31	**Reviewer**:	Ian Blackwell
MRID No.:	50749703	**Study Completion Date**:	10/24/2018
		Lab Study No.:	48826

Testing Laboratory: Product Safety Labs
Authors: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Tail, FIS2018.0256, "thick blue liquid"

Species: Sprague-Dawley-derived albino rats
Weight: 185-199 g **Age**:10-12 weeks
Source: SAGE Lab Animals

Conclusion:

1. LD_{50} (mg/kg):

Males=	Not tested
Females>	5,000 mg/kg b.w.
Combined=	Not tested

2. The estimated LD_{50} is greater than 5,000 mg/kg of body weight.
3. Tox. Category: IV **Classification**: Acceptable

Procedure (Deviations from §870.1100): None

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000	Not tested	0/3	Not tested

Observations: Reduced fecal volume, irregular respiration, anogenital staining, active and healthy.

Gross Necropsy: No gross abnormalities were noted.